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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,634	07/10/2001	Avi Ashkenazi	10466/67	1375

30313 7590 02/04/2004

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EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/902,634	<b>Applicant(s)</b> ASHKENAZI ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 39-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/27/3</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claim 39 has been amended as requested in the amendment of Paper filed on December 05, 2003 and claim 44 has been cancelled as requested in the amendment of Paper filed on May 27, 2003. Claims 39-43 are pending in the instant application.

Claims 39-43 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on May 27, 2003 and December 05, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Specification***

5. The instant specification stands objected to for those reasons of record in section 6 of Paper No. 13. Specifically because the capital letters are less than 0.21 cm in size, Tables 1-5 of the instant specification do not comply with 37 C.F.R. 1.52 (b). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

6. Claims 39-43 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those

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reasons of record in section 8 of Paper No. 13. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. Because the instant application does not disclose the biological role of this protein or its significance, an antibody to the protein cannot be considered particularly useful.

Applicant traverses the rejection first summarizing law on utility requirement (pages 10-11 of the Response). Applicant further submits that the utility of the instant claimed antibody is based on the asserted utility of the corresponding PRO266 polypeptide, which has been shown to induce “mononuclear cell, eosinophil and PMN infiltration into the site of injection of this peptide/protein into an animal” (page 12, first paragraph of the Response). Applicant argues that “a variety of real-life utilities are envisioned for PRO226 based on the proinflammatory cell infiltration assay results. Accordingly, antibodies raised against PRO226 can be exploited for their anti-inflammatory properties” (page 13). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

As fully explained in the previous office action, Examples 74 and 77 of the instant specification (pages 208-209 and 210, respectively), which present information about the ability of PRO226 to stimulate the proliferation of stimulated T-lymphocytes and induce inflammation in skin vascular permeability assay fail to provide any explanation regarding a correlation of this assay and any real-life diseases. There is no information regarding what subset of immune responses are targeted by PRO266 or, in the instant case, the antibodies to PRO226, and what is the significance of this particular response to a specific pathological condition or a disease. One skilled in the art readily understands that the assay described in Examples 74 and 77 is what is called in pharmacology a toxicity test. In the absence of any further research to evaluate the

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specificity and mechanisms of the recorded reaction, no extrapolation can be made to possibilities of using antibodies raised against PRO226 in “boosting an immune response” (page 13 of the Response).

The Examiner maintains that because the instant specification does not disclose a credible “real world” use for the claimed antibody, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

***Claim Rejections - 35 USC § 112***

7. Claims 39-43 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 9 of Paper No. 13.

***Claim Rejections - 35 USC § 103***

8. Claim 39 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Mochly-Rosen et al. (US Patent 5,519,003) for reasons of record in section 12 of Paper No. 13.

Applicant argues that “the ‘003 patent does not motivate one of skill in the art to make or use its antibodies for inhibiting an inflammatory response or as diagnostic agents for identifying inflammatory diseases” (page 16 of the Response). However, the antibody to a fragment of a polypeptide disclosed by Mochly-Rosen et al. to permit the detection of that polypeptide in a sample would be the same antibody that is encompassed by claim 39 because it would specifically bind the polypeptide of SEQ ID NO: 127, absent evidence to the contrary.

***Conclusion***

9. No claim is allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
February 2, 2004



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800